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2005 Update to the 2004 – 2006 STATE HEALTH PLAN

CERTIFICATE OF NEED REVIEW STANDARDS

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PURPOSE, AUTHORITY AND TECHNICAL NOTES

Purpose

The purpose of this document, which shall be referred to as the 2005 Update to the 2004-2006 State Health Plan, is to set forth the review criteria that shall be used when reviewing applications for certificates of need for consistency with plans pursuant to KRS 216B.040; and for determining whether a substantial change to a health service has occurred pursuant to KRS 216B.015(20)(a) and KRS 216B.061(1)(d).

Authority

KRS 216B.015(26) defines the "State Health Plan" to mean the document prepared triennially, updated annually and approved by the governor.

KRS 216 B.040 (2)(a)2, which requires the Cabinet for Health Services to establish criteria for the issuance and denial of certificates of need, limits such review to five considerations. The first such consideration is "consistency with plans" which requires that "each proposal approved by the Cabinet shall be consistent with the state health plan, and shall be subject to biennial budget authorizations and limitations, and with consideration given to the proposal's impact on health care costs in the Commonwealth."

Technical Notes

1. Unless otherwise noted, Area Development Districts (ADDs), are the geographic area for reviewing all applications for certificate of need.

2. Where applicable, an applicant shall set forth its plan for care of patients without private insurance coverage and its plan for care of medically underserved populations within the applicant's proposed service area.

3. In reviewing applications for certificates of need, the latest published version of the Cabinet for Health Services' *Inventory of Kentucky Health Facilities, Health Services, and Major Medical Equipment* and published utilization reports shall be used. Additions of equipment or services by existing licensed facilities which do not require certificate of need approval shall be included in the inventory of existing and newly approved facilities and services when such facilities and services become operational. Facilities which make such additions shall notify the Office of Certificate of Need within ten (10) days of such addition by completing Form #10 incorporated by reference in 900 KAR 6:050.

4. Health Services that are provided in private offices and clinics of physicians, dentists, and other practitioners of the healing arts which are exempt from certificate of need requirements pursuant to KRS 216B.020(2)(a) shall not be included in the *Inventory of Health Facilities, Health Services, and Major Medical Equipment*. In addition,

utilization of such services shall not be considered in the review of certificate of need applications for similar services.

5. Facilities owned or operated by the Commonwealth of Kentucky shall not be included in the inventory of licensed or approved acute, psychiatric, or long-term care beds.

6. All certificate of need decisions shall be made using that version of the State Health Plan in effect on the date of the decision, regardless of when the letter of intent or application was filed, or public hearing held.

7. Applications which have been granted nonsubstantive review status shall not be reviewed for consistency with this Plan.

8. The *Inventory of Kentucky Health Facilities, Health Services, and Major Medical Equipment* shall be available from the Office of Certificate of Need at 275 East Main St., Frankfort, Kentucky, 40621, (502) 564-9589 and at Web Site:http://chfs.ky.gov/ohp/con/

Review Criteria

Acute Care
Hospital Acute Care Beds

Definition

An acute care bed is defined as a hospital bed licensed by the Kentucky Office of Inspector General, Division of Community Health. A hospital utilizes acute care beds in providing medical services, including physician services and continuous nursing services for the diagnosis and treatment of patients who have a variety of medical conditions, both surgical and non-surgical.

Review Criteria

An application to add additional acute care beds shall be consistent with this plan if the following criteria are met:

1. The overall occupancy of acute care beds in the ADD exceeds the percentage computed by the following formula:

$$T_m = \frac{\Sigma (B_f \cdot T_f)}{B_m}$$

Where:

T_m = the minimum target occupancy for the ADD

Σ = is a summation sign, meaning "compute the total of what follows" for the ADD

B_f = the number of licensed and approved acute care beds for all facilities according to the ending date of the most recently published Inventory of Health Facilities, Health Services, and Major Medical Equipment.

T_f = the target occupancy percentage for a facility as determined by using Table 1 below. (B_f x T_f gives the targeted average daily census for a facility; summing these values gives the targeted average daily census for the ADD)

B_m = The number of licensed and approved acute care beds in the ADD (equals ΣB_f)

2. The applicant's overall acute care occupancy percentage of the hospital, as computed from the most recently published inventory and utilization data, exceeds the target occupancy percentages as shown in Table 1 as follows:

Table 1
Facility Target Occupancy Rates

Number of beds per Facility	Facility Target Occupancy Percentage (T_f)
1-50	60%
51 - 100	70%
101 - 200	80%
201 and above	85%

3. If the preceding two criteria are met and there is a need for additional beds equal to or greater than the number proposed, the maximum number of acute care beds that may be approved in the ADD shall be computed by the following formula:

$$X = (C \cdot \frac{A}{Tm}) - B$$

Where:

X = the maximum additional number of acute care beds

C = projected change multiplier for the ADD's service area population, computed by the following formula:

$$C = \Sigma (D_c \times \frac{P_{c5}}{P_{c0}})$$

Where:

D_c = the ADD's provider dependency for a county according to the most recently published data

P_{c5} = the county population projected five years into the future

P_{c0} = the county population at the time B_a was counted

Note: C will be 1 if there is no projected change in service area population, less than one if there is a projected decrease, and greater than one if there is a projected increase.

A = average daily census for the ADD as computed from the most recently published annual hospital utilization report

T_m = minimum occupancy target for the ADD (computed in assessment of need above)

B = the number of licensed acute care beds in the ADD plus any CON-approved changes in the number of acute care beds.

4. Notwithstanding criteria #1, 2 and 3, an application to add additional acute care beds shall be consistent with this plan if the following conditions are met:

a. The hospital can document that utilization has reached functional capacity. In calculating functional capacity, consideration shall be given to factors such as the mix of private and semi-private rooms, patient matching limitations such as gender or the needs for isolation beds required to address emergency patient needs, and limits created by special purpose acute units, such as obstetrics;

b. The hospital can document that transfer of beds from special purpose acute beds is not feasible because occupancy is greater than 65 percent or if the occupancy is less than 65 percent, the transfer of underutilized beds is not sufficient to meet the hospital's total additional acute care bed need;

c. The hospital can document an overall acute care occupancy rate in the county of 65 percent or greater for the 12 prior months;

d. The hospital can document that:

i. A new service established in the last eight years has resulted in increasing the number of inpatient days at the hospital by more than three percent, or;

ii A three percent or greater increase in inpatient volume has occurred from out-of-state admissions;

e. The maximum number of acute care beds that may be approved will be based on volume projected five years from CON filing. Approval will be based on the higher of:

i. The applicant's credible forecast of future utilization; or

ii. A regression analysis projection of patient day trends over a five-year timeframe.

5. If the most recently published data indicates that the occupancy for existing acute care beds for the applicant's facility was 60% or greater, an application to convert psychiatric and/or CD beds to acute care shall be consistent with this plan if the application meets either of the following conditions:

a. The applicant meets the review criteria in Criteria 1, 2 and 3 above, or

b. The applicant has existing licensed acute care and psychiatric care and/or chemical dependency beds, and:

i. All of the proposed acute care beds are being converted from licensed psychiatric and/or chemical dependency beds;

ii. The occupancy of psychiatric and/or chemical dependency beds is less than 60% as computed from the latest published data; and

iii. The additional acute care beds will be converted and implemented on site at the applicant's existing licensed acute care facility.

6. With the exception of neonatal beds, facilities with existing specialized beds, such as ICU/CCU and OB/GYN beds, may convert licensed acute care beds for use as additional beds for existing specialized services without CON approval, if the addition of these specialized beds will not result in an increase in total licensed acute care beds in the facility.

Special Care Neonatal Units

Definition

Special Care Neonatal beds are licensed acute care beds located in hospital neonatal units that provide care and treatment of newborn infants through the age of 28 days, and longer if necessary.

Review Criteria

An application for a certificate of need for Level II special care neonatal beds shall be consistent with this plan if the following criteria are met:

1. Approval of the application does not cause the number of Level II beds to exceed the following calculation:

(Total annual ADD births[1] ÷ 1000) • 3 = Maximum number of Level II beds in the ADD;

[1] As reported in the most recent *Kentucky Hospital Utilization and Services Reports.*

2. The number of Level II beds in a facility shall be eight (8) per unit except in those cases where population distribution and access to Level II services justify a smaller unit. In no case shall a unit be smaller than four (4) beds;

3. The Cabinet determines that more Level II beds than indicated by the above calculation are justified in order to allow for the presence in the ADD of hospitals that provide a higher intensity of neonatal care than that provided by most hospitals due to a high percentage of neonatal patient referrals for complications that cannot be handled at the primary care level;

4. No new Level II program shall be approved in an ADD unless the over-all utilization of existing providers of Level II services in the ADD is at least 75 percent as computed from the most recently published inventory and utilization data;

5. No additional beds will be approved for an existing unit unless the utilization in this unit is at least 75% as computed from the most recently published inventory and utilization data;

6. Hospitals proposing to add acute care beds to be utilized as Level II shall be required to meet all criteria in the Hospital Acute Care Bed component with the exception of criterion 1; and

7. In order to be consistent with these standards, an application for Level II and Level III special care neonatal beds shall also document consistency with the *Guidelines for Perinatal Care, Third Edition*, published jointly by the American Academy of Pediatrics and the American College of Obstetrics and Gynecology. These *Guidelines* are incorporated into these standards by reference.

An application for a certificate of need for Level III special care neonatal beds shall be consistent with this plan if:

1. Approval of the application does not cause the number of Level III beds in the State to exceed the following calculation:

(Total annual state births[1] ÷ 1000) • 1 = Maximum number of Level III beds in the state)

2. The Cabinet determines that more Level III beds than indicated by the above calculation are justified in order to allow for the presence of hospitals that provide a higher intensity of neonatal care than that provided by most hospitals due to a high percentage of neonatal patient referrals for specialized services such as open-heart surgery, transplants, etc.;

3. No new Level III program shall be approved in the ADD unless the over-all utilization of existing providers of Level III services in the ADD is at least 75 percent as computed from the most recently published inventory and utilization data;

4. No additional beds shall be approved for an existing unit unless the utilization of this unit is at least 75% as computed from the most recently published inventory and utilization data;

5. Hospitals proposing to add acute care beds to be utilized as Level III (three) shall be required to meet all criteria in the Hospital Acute Care Bed component with the exception of criterion 1; and

6. In order to be consistent with these standards, an application for Level III special care neonatal beds shall also document consistency with the *Guidelines for Perinatal Care, Third Edition*, published jointly by the American Academy of Pediatrics and the American College of Obstetrics and Gynecology. These *Guidelines* are incorporated into these standards by reference.

Ambulatory Surgical Centers

Definition

An Ambulatory Surgery Center is a free standing health facility where scheduled procedures which are billed as surgical procedures, to include cystoscopy procedures, are performed, and which meet the licensure requirements of the Cabinet for Health and Family Services.

Review Criteria

An application for outpatient surgical services which will result in the establishment of an additional licensed ASC shall be consistent with the state health plan only if the following criteria are met:

1. Overall inpatient and outpatient surgical utilization in hospitals and ambulatory surgical centers (ASC) is at least 85% in the planning area as computed from the most recently published inventory and utilization data. With regard to surgical services, the planning area shall be comprised of the county of the proposal and all contiguous counties;

2. Inpatient and outpatient surgical utilization is computed using an average 2.0 hours (including cleanup time) per in-patient surgery and 1.2 (including cleanup time) per outpatient surgery, and 2,205 potential surgical hours per year as follows:

   $$\frac{\text{(Total inpatient operations x 2.0) + (Total outpatient operations x 1.2)}}{\text{(Existing and Approved Hospital Operating Rooms + ASC Operating Rooms x 2,205)}}$$

   Applicants proposing outpatient surgical services may use actual documented surgical time to calculate institution-specific utilization rates. Outpatient operations are the sum of all hospital outpatient and ambulatory surgical center operations;

3. All new ambulatory surgery centers shall be located within twenty (20) minutes normal driving time of at least one full-service hospital and the applicant shall have a transfer agreement for the proposed center in place with at least one full-service hospital which is located within twenty (20) minutes normal driving time of the center;

4. Overall surgical utilization in the planning area notwithstanding, an application to establish an ambulatory surgery center limited to

a specific type of procedure shall be consistent with this plan if the following conditions are met:

(a) The applicant documents that patients are not receiving the specific type of surgical procedures (as identified by procedure codes) proposed by the applicant at facilities in the planning area; and

(b) The application contains an explanation of why the unmet need for the specific type of surgical procedure has not been reasonably addressed by providers in the planning area.

Open Heart Surgery Program

Definition

Open-heart surgery is any surgical procedure involving the heart, performed to correct acquired or congenital defects, to replace diseased valves, to open or bypass blocked vessels, or to graft a prosthesis or a transplant in place. In open-heart procedures, the heart chambers are open and fully visible, and blood is detoured around the surgical field by a heart-lung bypass machine unless the procedure involved is a minimally invasive coronary artery bypass graft, in which case a heart-lung machine might not be used, but must still be available in the operating room on a stand-by basis. A "case" is defined as the entire episode of treatment in the operating room regardless of the number of procedures performed.

Review Criteria

An application for a certificate of need for an open heart surgery program shall be consistent with this plan if the following criteria are met:

1. For adult open heart surgery, there is not an existing or approved open heart surgery program in the ADD or the following criteria are met:

   a. Every open heart surgery program in the ADD listed in the Cabinet's most recently published Hospital Utilization Report performed at least 400 adult open-heart surgeries per year;

   b. Every open heart surgery program listed in the Cabinet's most recently published Hospital Utilization Report that is within 50 miles of the proposed site as reflected in the most recently published Kentucky Official Highway Map performed at least 400 adult open-heart surgeries per year;

c. Every open heart surgery program in the ADD that is not listed in the Cabinet's most recently published Hospital Utilization Report performed at least 300 adult open-heart surgeries in the past 12 months;

d. Every open heart surgery program that is within 50 miles of the proposed site as reflected in the most recently published Kentucky Official Highway map that is not listed in the Cabinet's most recently published Hospital Utilization Report performed at least 300 adult open-heart surgeries in the past 12 months.

e. The applicant shall document that at least 400 adult open-heart procedures will be performed during the third year of operation. These projections must consider historical number of diagnostic cardiac catheterization procedures performed at the applicant hospital, the Kentucky statewide ratio of open heart surgeries to diagnostic catheterization procedures as calculated in the latest published inventory and utilization data, and documentation of the number of diagnostic catheterization patients referred for open heart surgery from the applicant hospital during the most recent 12 month period;

f. The applicant shall document that the approval of the proposed program will not cause any existing program in the ADD or any other open heart surgery program within 50 miles of the proposed site as reflected in the most recently published Kentucky Official Highway Map to fall below 400 cases annually when considering historical trends in utilization, referral patterns for such services to existing providers, and commonality of medical staffs;

g. The applicant shall demonstrate that the projected number of therapeutic cardiac catheterization procedures will reach at least 350 by the third year of operation of the open heart surgery program. These projections must consider historical diagnostic cardiac catheterization procedures at the applicant hospital, the Kentucky statewide ratio of therapeutic catheterizations to diagnostic catheterizations patients and documentation of the historical number of diagnostic cardiac catheterization patients referred from the applicant hospital for therapeutic cardiac catheterization during the most recent 12 month period. Applicants shall also document compliance with the requirements for therapeutic catheterization under the Cardiac Catheterization Services chapter, criterion 9, of these Review Standards;

h. The applicant shall consider the impact on the projected volume of cases and the need for an additional open heart program in Kentucky which results from the existence of open heart surgery in nearby cities of bordering states that are customarily used by Kentucky residents;

i. The applicant shall document that the *Guidelines for Coronary Artery Bypass Graft Surgery* adopted by the American College of Cardiology and the American Heart Association will be followed; and

j. The applicant must identify the surgeon who will be the primary attending surgeon in the open heart service. Further, the applicant must also provide information regarding this individual's background and experience concerning open heart surgery, and this individual's availability to care for open heart patients in the event of emergencies.

2. For pediatric open heart surgery:

a. Only pediatric teaching facilities shall be approved for pediatric open heart surgery;

b. Using the most recently published inventory and utilization data available, every existing pediatric program in the state shall be performing, and shall be projected to continue to perform at least 150 pediatric open-heart surgeries per year;

c. The applicant shall document that at least 100 pediatric open-heart procedures will be performed during the third year of operation.

Organ Transplant Program

Definition

Transplant procedures involve the transfer of an organ or tissue from one person to another, or from one body part to another, to replace a diseased structure, to restore function, or to change appearance. Skin and kidneys are among the more commonly transplanted structures; others include hearts, livers, lungs, pancreas, cartilage, bone marrow, corneal tissue, portions of blood vessels and tendons.

Review Criteria

An application for a certificate of need for an organ transplant program shall be consistent with this plan if the following criteria are met:

1. The applicant documents whether the numbers of transplants being performed by comparable transplant programs in the Commonwealth are sufficient for consistency with nationally accepted volume and quality standards for each type of transplant program; the record of medical outcomes by those programs; and the impact on need for additional transplant programs in Kentucky resulting from the existence of transplant programs in nearby cities of bordering states that are customarily and significantly used by Kentucky residents;

2. The applicant documents that it has the ability to meet nationally accepted volume and quality standards, as well as those factors that impact patient care and overall cost, quality and outcomes of service delivery, including demographic and epidemiological factors;

3. For pediatric programs, the pediatric program shall be provided in a pediatric teaching facility which has the availability of physician specialty support and specialized ancillary support services; and

4. The applicant demonstrates that organ allocation for patients awaiting transplantation shall be performed in accordance with federally mandated guidelines.

Diagnostic and Therapeutic Equipment and Procedures
Cardiac Catheterization

Definition

Cardiac catheterization is a diagnostic or therapeutic procedure in which a catheter is introduced into a large vein or artery, usually of an arm or a leg, and threaded through the circulatory system to the heart. A single procedure lasts from the time the catheter is inserted until the time that the catheter is completely withdrawn from the patient.

Review Criteria

An application for a certificate of need for a cardiac catheterization laboratory shall be consistent with this plan if the following review criteria are met:

1. For applicants proposing fixed site diagnostic cardiac catheterization only:

    a. Using the most recently published inventory and utilization data available, each existing fixed-site diagnostic laboratory in the ADD shall have performed at least 500 diagnostic procedures in the last 12 month reporting period. Each existing fixed-site comprehensive laboratory (diagnostic and therapeutic) shall have performed at least 1,100 diagnostic equivalent procedures in the last 12 month reporting period; each mobile unit which performs catheterizations at sites located within 50 miles shall have performed a number of procedures at each location based on the ratio of hours in operation in proportion to the required 500 diagnostic procedures annually. Laboratory utilization shall be determined by counting all therapeutic, pediatric or electrophysiology studies as two diagnostic equivalent procedures each and other procedures as one diagnostic equivalent procedure each. For diagnostic catheterizations, only one diagnostic procedure will be counted per patient episode in the cardiac catheterization laboratory regardless of the number of procedures performed;

    b. The total projected number of diagnostic catheterizations in the ADD shall exceed the total existing procedures by at least 500 procedures during the third year of operation.

        i. The total projected number of procedures will be based on the diagnostic cardiac catheterization use rate for the Commonwealth of Kentucky for the most recent 12 month period for which data are available applied to the

projected ADD population three years in the future from the date the application was filed;

ii. The number of diagnostic cardiac catheterization procedures performed by existing programs in the most recent 12 month reporting period according to the most recently published inventory and utilization data will be subtracted from the total projected diagnostic procedures for the ADD. If there are approved but not operational fixed-site laboratories or lab not included in the most recently published Hospital Utilization Report, an additional 500 procedures will be subtracted from the total for each.

2. For applicants proposing comprehensive (diagnostic and therapeutic) cardiac catheterization services:

a. Using the most recent published inventory and utilization data available, each existing comprehensive laboratory in the ADD shall have performed at least 1,100 diagnostic equivalent procedures in the last 12 month reporting period, which is approximately 85% of the 1,333 hour-and-a-half procedures possible in 50 weeks of 40 hours each. Laboratory utilization shall be determined by counting all therapeutic, pediatric or electrophysiology studies as two diagnostic equivalent procedures each, and other procedures as one diagnostic equivalent procedure each. For diagnostic catheterizations, only one diagnostic procedure will be counted per patient episode in the cardiac catheterization laboratory regardless of the number of procedures performed;

i. The total projected number of procedures shall be based on the total cardiac catheterization use rate for the Commonwealth of Kentucky for the most recent 12 month period] using the most recently published inventory and utilization data applied to the projected ADD population three years in the future from the date of the application.

ii. The total number of cardiac catheterization procedures performed by existing programs in the most recent 12-month reporting period shall be subtracted from the total projected catheterization procedures for the ADD. If there are approved but not operational laboratories or labs not included in the most recently published Hospital Utilization Report, an additional 500 procedures shall be subtracted from the total for each.

3. For applicants proposing mobile adult diagnostic cardiac catheterization services only:

   a. Using the most recently published inventory and utilization data available, each existing fixed-site diagnostic laboratory located within 50 miles of the proposed laboratory shall have performed at least 500 diagnostic procedures in the last 12 month reporting period. Each existing comprehensive laboratory within 50 miles of the proposed laboratory shall have performed at least 1100 diagnostic equivalent procedures in the last 12-month reporting period. Each existing mobile diagnostic cardiac catheterization service located within 50 miles of the proposed laboratory shall have performed at that location a number of procedures based on the ratio of hours in operation at that location in proportion to the required 500 diagnostic procedures annually. Laboratory utilization shall be determined by counting all therapeutic, pediatric, or electrophysiology studies as two diagnostic equivalent procedures each, and other procedures as one diagnostic equivalent procedure each. For diagnostic catheterizations, only one diagnostic procedure will be counted per patient episode in the cardiac catheterization laboratory regardless of the number of procedures performed;

   b. There is not a newly approved cardiac catheterization laboratory in the ADD which was not operational as of the date of the most recently published data; and

   c. There is not a newly approved cardiac catheterization laboratory in the ADD that began operating subsequent to the date of the most recently published utilization report that did not perform the number of diagnostic or diagnostic equivalent procedures as set forth in 3.a. above.

4. For applicants proposing therapeutic catheterization (except for the use of clot-dissolving infusion drugs approved by the FDA such as Streptokinase and TPA) the facility shall have a comprehensive cardiac surgical program (including open-heart surgery) within the facility;

5. For applicants proposing a pediatric cardiac catheterization laboratory, the facility shall also offer a pediatric cardiac surgical program and a Level III neonatal intensive care unit and shall document that 60,000 live births were reported to have occurred in the most recent annual hospital utilization and services report;

6. For all cardiac catheterization laboratories, the laboratory shall be used only for catheterization and angiographic studies (cerebral, coronary, renal, etc.);

7. For all cardiac catheterization laboratories, the applicant shall maintain a utilization review program (including record keeping) relating to medical

necessity, quality, mortality, morbidity, number of cardiac catheterizations that require repetition due to inability to read the data, and other considerations generally accepted as appropriate for review;

8. For all cardiac catheterization laboratories, the applicant shall document that the most recent national guidelines as established by the Ad Hoc Task Force on Cardiac Catheterization of the American College of Cardiology/American Heart Association and published in *ACC/AHA Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories* will be followed. This report sets guidelines for administration, space, equipment, personnel and working arrangements for diagnostic and therapeutic cardiac catheterization laboratories;

9. For all cardiac catheterization laboratories, the applicant shall document that each physician is projected to perform at least 150 successful diagnostic procedures per year with acceptable mortality and morbidity in patients who warrant the procedure;

10. For a comprehensive cardiac catheterization laboratory that provides therapeutic catheterizations, the applicant shall also document that:

    a. Training for percutaneous transluminal coronary angioplasty (PTCA) will follow the guidelines set forth in the Bethesda Conference on Adult Cardiology Training (Journal of the American College of Cardiology, 1986; 7: 1191-218), as revised, which require extra training beyond the two years for clinical cardiology;

    b. Each physician is projected to perform at least 75 successful angioplasties per year with acceptable mortality and morbidity in patients who warrant the procedure.

11. Notwithstanding the foregoing review criteria, an application proposing therapeutic catheterization services shall be consistent with this plan if there is not an existing or approved therapeutic catheterization service (except for use of the clot-dissolving infusion drugs approved by the FDA such as Streptokinase and TPA) in the ADD.

Magnetic Resonance Imaging

Definition

Magnetic resonance imaging (MRI) means a diagnostic imaging modality which utilizes magnetic resonance, an interaction between atoms and electromagnetic fields, to project images of internal body structures.

Review Criteria

1. Hospitals without MRI service.

Applications to establish MRI services at a hospital currently without the authority to provide MRI services shall be consistent with this Plan provided that the MRI service is provided under the hospital's existing hospital license. Once approved, MRI services may be provided with either a fixed or mobile unit.

2. Hospital-owned clinics licensed as ambulatory care clinics and hospital-owned clinics licensed as specialized medical technology service clinics.

a. Applications to establish MRI services at a hospital-owned clinic licensed as an ambulatory care clinic or a specialized medical technology service shall be consistent with this Plan provided that the clinic is recognized as a hospital provider based entity under Medicare or will be recognized as a hospital provider based entity under Medicare upon implementation and is located in the same county as the hospital.

b. Applications from hospitals to establish MRI services at a yet to be established clinic shall be consistent with this Plan provided that the applicant documents that:

- The hospital is currently authorized to provide MRI services under its hospital license.
- The clinic will be and will remain solely owned by the same entity as the hospital;
- The clinic will be located within the same county as the hospital;
- The clinic will become licensed as an ambulatory care clinic or a specialized medical technology clinic; and
- The clinic will become and will remain a Medicare recognized hospital provider based entity.

3. No other applications for Magnetic Resonance Imaging services shall be found to be consistent with this Plan.

Megavoltage Radiation Equipment

Definition

Megavoltage radiation equipment is used in the treatment of cancer. For the purposes of this plan, megavoltage radiation equipment includes units such as linear accelerators and Cobalt-60 units that operate at two or more megavolts and deliver external radiation.

Review Criteria

No application for megavoltage radiation equipment shall be found to be consistent with this Plan.

Comprehensive Physical Rehabilitation Hospital Beds

Definition

For purposes of this plan there shall be one category of rehabilitation beds called "comprehensive physical rehabilitation beds" which may be located in free-standing facilities or as units in acute care hospitals that provide therapy and training for rehabilitation. Such facilities offer a range of services that may include occupational therapy, physical therapy, and speech therapy to aid in the restoration of an individual or a part to normal or near normal function after a disabling disease or injury.

Review Criteria

An application for a certificate of need for comprehensive physical rehabilitation beds shall be consistent with this plan if the following criteria are met:

1. An applicant that does not have existing licensed or certificate of need approved comprehensive physical rehabilitation beds and is proposing to establish such beds, shall demonstrate that the overall occupancy for comprehensive physical rehabilitation beds in the ADD exceeds 85 [~~75~~] percent as computed from the most recently published rehabilitation inventory and utilization data;

2. Applicants proposing to expand the number of existing licensed comprehensive physical rehabilitation beds shall demonstrate that the occupancy of the existing comprehensive physical rehabilitation beds in the applicant's facility exceeds 85 [~~75~~] percent as computed from the most recently published rehabilitation inventory and utilization data;

3. If criterion (1) or (2) is met, the maximum number of beds that may be approved in the ADD shall be computed by the following formula:

   $$N = [(PD \div P) \times PP \div (365 \times .75)] - (LB + AB)$$

   Where:
   N = Need for Comprehensive Rehabilitation Beds in the ADD.
   PD = The number of inpatient days in comprehensive physical rehabilitation beds statewide as reported in the most recently published data.
   P = Estimated population in the state for the period used to derive patient days.
   PP = Estimated 2004 population for the ADD.

.75 = The desired average annual occupancy rate for comprehensive physical rehabilitation beds in the ADD.
LB = Existing licensed comprehensive physical rehabilitation Beds in the ADD.
AB = The number of comprehensive physical rehabilitation beds in the ADD for which a Certificate of Need has been granted.

For purposes of (1), (2) and (3) of this section, any additional comprehensive physical rehabilitation beds for which a certificate of need has been granted for an ADD within three calendar years prior to the public hearing on the application, but which were not operational during the period covered by the semiannual utilization report, shall also be treated as "beds in operation" in calculating the utilization rate for the ADD. Any other licensed or approved beds not in operation according to the semiannual utilization report shall be excluded from the calculation.

4. The Cabinet may approve more rehabilitation beds than indicated by the need formula to allow for the presence of hospitals that provide a higher intensity of rehabilitation services than provided by most rehabilitation hospitals due to the in-migration of out-of-state patients or a high percentage of patient referrals for specialized services from other ADDs.

5. The minimum size for a new freestanding rehabilitation hospital shall be 40 beds and the minimum size for a new rehabilitation unit in an acute care hospital shall be 20 beds.

Mental Health Care

Chemical Dependency Treatment Beds

Definition

Chemical dependency treatment beds are licensed beds used in the treatment of patients suffering from abuse or addiction to chemical substances such as alcohol or drugs.

Review Criteria

An application for a certificate of need for chemical dependency beds shall be consistent with this plan if the following criteria are met:

1. The number of chemical dependency beds in an ADD shall not exceed a maximum rate of 11.4 beds per 100,000 geographic population;

2. Consideration shall be given to the availability of acute or psychiatric beds designated for use as chemical dependency beds, as well as the availability of KRS Chapter 222 program beds;

3. Applications to develop hospital-based units using existing space shall be given priority over applications for new construction;

4. In ADDs with a rate below the maximum for chemical dependency beds, all or a portion of the bed quota for contiguous ADDs may be used if the applicant demonstrates that:

    a. the proposed facility will be available and accessible to the population or a portion of the population of the contiguous ADDs,

    b. linkage agreements have been made with appropriate providers in the contiguous ADDs, and

    c. letters of support have been obtained from the contiguous ADD.

Psychiatric Hospital Beds

Definition

Psychiatric beds are those licensed beds which are located in psychiatric hospitals or as units in an acute care hospital and are used for treatment of inpatients that require psychiatric or mental health care, including medical care and treatment of mental, emotional, and behavioral disorders.

Review Criteria

An application for a certificate of need for psychiatric beds for adults, children and adolescents shall be consistent with this plan if the following criteria are met:

Psychiatric Services

1. Licensed and approved psychiatric beds in an ADD shall not exceed 0.4 beds per 1,000 geographic population. Statewide psychiatric care facilities operated by the Commonwealth shall not be counted in the existing bed count;

2. Any acute care facility proposing the addition of psychiatric beds shall exceed the target occupancy rates shown in Table 1 below for its licensed acute care beds for the most recent 12 month period reported in the most recently published utilization and inventory data, unless all the proposed additional psychiatric care beds are being converted from licensed acute care beds;

Table 1

Facility Target Occupancy Rates

# Beds in Facility	Target Occupancy
1-50	60%
51-100	70%
101-200	80%
201 and above	85%

3. No additional psychiatric beds shall be approved unless overall occupancy for all psychiatric beds in the ADD exceeds the target occupancy rates shown in Table 1 for the most recent 12 month period in the latest published inventory and utilization report. An exception can be made when a facility demonstrates that occupancy is below the target due to a need to keep a number of vacant beds available for statewide emergencies.

4. If the most recently published hospital utilization and inventory data indicate that the occupancy for existing psychiatric beds for an applicant's facility was 70% or greater, an application to convert acute care beds to psychiatric beds shall be consistent with this plan if the application meets either of the following conditions:

   a. The applicant meets the review criteria in Sections 1, 2, and 3 above, or

   b. The applicant has existing licensed acute care beds and psychiatric care beds, and:

      i. All of the proposed psychiatric care beds are being converted from licensed acute care beds;

      ii. ii The occupancy of acute care beds is less than 70% in the latest published utilization and inventory data; and

      iii. The additional psychiatric beds will be converted and implemented on site at the applicant's existing licensed acute care facility.

5. If the most recently published hospital utilization and inventory data indicate that the occupancy for existing psychiatric beds for an applicant's facility was 70% or greater, an application to convert chemical dependency beds to psychiatric beds shall be consistent with this plan if the application meets either of the following conditions:

   a. The applicant meets the review criteria in Sections 1, 2, and 3 above, or

b. The applicant has existing licensed chemical dependency beds and psychiatric care beds, and:

i. All of the proposed psychiatric care beds are being converted from licensed chemical dependency beds;

ii. ii The conversion will not impede access to appropriate care for patients needing treatment for abuse or addiction to chemical substances such as alcohol or drugs; and

iii. The additional psychiatric care beds will be converted and implemented on site at the applicant's existing licensed acute care or chemical dependency facility.

Psychiatric Services for Children and Adolescents

1. No new psychiatric beds for children or adolescents shall be approved except for beds converted from existing acute care beds. New hospital psychiatric beds for children or adolescents shall focus on short-term (under 30 days) crisis stabilization. Small, specialized programs are preferred to larger programs;

2. A facility proposing to provide inpatient psychiatric care for children 12 years of age and younger shall have on staff a board-eligible or board-certified child psychiatrist who maintains responsibility for admissions and treatment. For the purposes of this section, a board-eligible child psychiatrist is a doctor of psychiatry who has been board-certified in general psychiatry by the American Board of Psychiatry and Neurology and has completed a two-year fellowship in child psychiatry;

3. An application for new psychiatric beds for children or adolescents shall include all of the following:

a. The specific number of beds proposed for each age;

b. An inventory of current services in the ADD;

c. Clear admission and discharge criteria consistent with a short-stay program and least restrictive treatment;

d. Linkage agreements with other agencies in the proposed service areas, including all regional interagency councils (RIACs), community mental health centers, the Department for Social Services, and major referring school systems. These agreements should demonstrate a commitment by these agencies and the hospital to joint treatment and discharge planning as appropriate;

e. Documentation of provision for case management when necessary after discharge. (Case managers need not be on the hospital's staff, but should be closely involved in cases from treatment planning onward).

Geriatric Psychiatric Services

1. Notwithstanding criteria 1, 2, 3 and 4, applications proposing to establish non-medicaid inpatient geriatric psychiatric programs in an existing licensed acute care facility located in a county that has no existing inpatient geriatric psychiatric program shall be considered consistent with the State Health Plan if the following conditions are met:

   a. The occupancy of acute care beds in the applicant's facility is less than 70 percent in the latest published utilization report;

   b. All of the proposed psychiatric care beds are being converted from licensed acute care beds;

   c. All of the psychiatric care beds will be converted and implemented on site at the applicant's existing licensed acute care facility;

   d. All of the converted psychiatric care beds shall be dedicated exclusively to the treatment of geriatric patients, aged 65 or older;

   e. The hospital shall establish district admission and discharge criteria for admitting only those patients who have both mental and physical conditions who would be excluded from treatment in a regular adult psychiatric unit;

   f. The staff of the unit shall include a multidisciplinary team of specialists involving psychiatry and internal medicine with specialization in the treatment of geriatrics and nursing personnel specially trained in psychiatric and medical geriatric patient care;

   g. The number of beds to be converted shall be based on the population age 65+ in the counties proposed to be served;

   h. The applicant agrees in writing not to seek medicaid certification for the converted beds.

Psychiatric Residential Treatment Facilities

Definition

Psychiatric residential treatment facilities are licensed, community-based, and home-like facilities with a maximum of eight beds which provide inpatient psychiatric residential treatment to residents who have an emotional disability or severe emotional disability as defined

in KRS 200.503, age six years to 21 years with an age range of no greater than 5 years in a living unit.

Review Criteria

An application for a certificate of need for a psychiatric residential treatment facility shall be consistent with this plan if the following criteria are met:

1. The number of PRTF beds shall not exceed 16 beds in any ADD with less than 275,000 population, 32 beds in any ADD with 275,000 to 550,000 population, and 48 beds in any ADD with over 550,000 population.

2. An application to add PRTFs shall include the following:

    a. an analysis of the number and characteristics of persons ages 6 to 21 in the proposed service area who have problems which require this level of care;

    b. an inventory of all types of treatment-oriented residential programs and alternatives that meet a portion of the need for PRTFs in the proposed service area, whether or not the programs are licensed as PRTFs ;

    c. clear admission and discharge criteria, including age, sex, and other limitations;

    d. a discussion of anticipated length of stay, with distinctions in the program or physical plant whenever all or a portion of a facility will be used to serve patients needing short-term crisis care; and

    e. linkage agreements with other agencies in the proposed service area, including all Regional Interagency Councils (RIACs), at least one hospital having a psychiatric unit that serves children, Community Mental Health Centers, the Department for Social Services, and local school systems. These agreements should demonstrate a commitment of agencies and the PRTF to joint treatment and discharge planning as appropriate.

3. While PRTFs need not restrict admissions to persons living in the same ADD or service area as the PRTF, priority shall be given to applications which state that priority for admission will be given to referrals made by RIACs in the applicant's service area that otherwise meet the admission criteria of the PRTF.

4. Priority shall be given to applications that demonstrate access to an array of other community-based services and post-placement alternatives (e.g., day treatment, therapeutic foster homes, staffed community residences).

Ambulance Services

Definition

Ground ambulances include Class I, II, or III, providers based on the level of care for which the provider has been licensed. Class I ground ambulance services provide basic life support or advanced life support services to all patients for both emergencies and scheduled ambulance transportation which is medically necessary. Class II ground ambulance services provide only basic life support services but do not provide initial response to the general population with medical emergencies and which are limited to providing scheduled ambulance transportation which is medically necessary. Class III ground ambulance services provide mobile intensive care services at or above the level of advanced life support to patients with critical illnesses or injuries who must be transported between hospitals in vehicles with specialized equipment as an extension of hospital-level care. These ambulance classes are set forth in KRS 211.952.

Review Criteria

An application for a certificate of need for ground ambulance services shall be consistent with this plan if the following criteria are met:

1. The applicant shall document that the appropriate local legislative body (fiscal court, city council, or both when applicable) has been given notice of the applicant's intent to obtain a certificate of need. Such notice shall describe the scope of service and proposed service area. For purposes of this requirement, the term "appropriate local legislative body" refers only to those legislative bodies that are currently licensed to provide ambulance services in the applicant's proposed service area;

2. In the event of competing applications to ADD services in the same service area, preference shall be given to an application proposing the higher level of service. If multiple providers propose ALS services, then preference shall be given to the applicant who most thoroughly documents need for the service and presents ability to meet the need;

3. Applications to provide only Class II or Class III services shall be accompanied by documentation (e.g., charts depicting response times of existing service, number of runs during the previous year, and comparable supportive data) that the need for scheduled or critical care inter-facility transportation is not being met by the existing emergency or other Class II or III ground ambulance services. In the presence of such evidence, priority shall be given to a competing application(s), if any, for the addition of vehicles, expansion of service areas, or comparable modifications that would allow an existing emergency ambulance service provider(s) to meet any unmet need for critical care interfacility or scheduled ambulance services.

Home Health

Definition

"Home health" refers to a combination of health care and social services provided to individuals in their homes or in other community and homelike settings pursuant to 902 KAR 20:081.

“To establish a home health service” means to establish a parent home health agency or a subunit as defined by Medicare in a county where the applicant is not currently licensed to serve.

"To expand a home health service" means to add to the applicant's existing service area a county or counties which are contiguous to the applicant’s existing service area provided that the expansion does not involve the establishment of a parent home health agency or subunit as defined by Medicare.

The need for home health services is determined on a county-by-county basis by applying target rates estimating the number of individuals per 1,000 population expected to require home health services. Target rates are calculated for the plan year and are based on the statewide average annual number of unduplicated patients served in each age cohort as reported for the most recent two calendar years in the Home Health Services Reports. The inventory for patients expected to be served will be adjusted by the addition of 125 patients for each certificate of need approved to establish a new agency or subunit in a specific county, by 75 patients for each application approved to expand a home health service to a specific county, and by 50 patients for each application approved for a hospital to establish an agency to solely serve the county in which the hospital is located. The respective number of patients will be removed from the inventory for patients to be served when the latest Home Health Services Report indicates that the agency has served patients in the approved county.

Age cohort rates are applied to the year 2005 county population projections to determine projected need for home health services. The number of additional patient services needed in a county is then determined by subtracting the average annual number of unduplicated patients served in the county as reported for the most recent two calendar years in the Home Health Services Reports from actual projected need.

Review Criteria

1. An application for a certificate of need to establish a home health service shall be consistent with this Plan if there is a projected need for at least 125 additional patients needing home health care services in the county for which the application is made as shown in the Cabinet's most recently published home health projections.

2. An application for a certificate of need to expand a home health service currently licensed in Kentucky shall be consistent with the Plan if there is a projected need for at least 75 additional patients needing home health care services in the county for which

the application is made as shown in the Cabinet's most recently published home health projections.

3. An application for an existing acute care hospital located in a non-metropolitan statistical area to establish a home health service to serve solely the county in which the acute care hospital is located shall be consistent with the Plan if the applicant documents that it will serve at least 50 patients in the county and will enhance the continuity of care in the county.

Hospice

Definition

Hospice programs provide symptom relieving care and supportive services through an interdisciplinary approach that addresses the physical, spiritual, social, and economic needs of terminally ill patients and their families. Services include home care, inpatient care, bereavement services, counseling, and education. The family is considered the unit of care. Emphasis is placed on symptom control and pain control for the terminally ill person, support for the patient before death, and support for the family before and after death.

Review Criteria

An application for a certificate of need for hospice services shall be consistent with this plan if:

1. The sum of the following computation for all proposed counties exceeds existing service levels by 150 or more patients per year:

    a. 55% of the mean annual number of cancer deaths in the hospice combined service area during the preceding two years; and

    b. 12% of the mean annual number of deaths from all other non-traumatic causes in the hospice combined service area during the preceding two years.

Or, if:

2. The applicant documents the existence of at least one of the following conditions:

    a. absence of services by a hospice certified for Medicaid and Medicare, and evidence that the applicant will provide Medicaid- and Medicare-certified hospice services in the area; or

    b. absence of services by a hospice that serves patients regardless of the patient's ability to pay, and evidence that the applicant will provide services for patients regardless of ability to pay.

Adult Day Health Care

Definition

Adult day heath is the provision of outpatient health care services that meet the health care needs of patients for a regular number of hours per day in conformance with physicians orders and without which would cause the patient and patient's health to meet the criteria for nursing home level of care.

Review Criteria

An application for a certificate of need for an Adult Day Health program shall be consistent with this plan if the following criteria are met:

1. Evidence is presented that the following services will be provided:

    - One meal per day including special diets;
    - Snacks as appropriate;
    - Daily on-site nursing services and supervision provided by RN or LPN including administration of medications and treatments as ordered by a patient's physician;
    - Regularly scheduled activities specific to patient's age and care plan;
    - Routine services required to meet daily personal care and health care needs;
    - Equipment essential to the provision of Adult Health Care Services and incidental supplies necessary to provide Adult Day Health Care services;

2. Evidence is presented of the capacity of providing necessary transfer and referral services should a patient's needs become such that a different level of care would be more beneficial;

3. Evidence is presented of the capacity of keeping appropriate medical records and following accepted universal precaution practices.

Long-Term Care Beds

Nursing Facility Beds

Definition

The term "nursing facility bed" shall mean skilled nursing (SN) beds, intermediate care (IC) beds, nursing facility (NF) beds, nursing home (NH) beds and Alzheimer facility (AF) beds [1] .

For purposes of this Plan the term "need" shall mean a quantitative analysis which focuses on long-range plans to provide nursing facility bed services to an entire population. The term "demand" shall mean an immediate preference on the part of an individual to live in a particular nursing facility.

Need Assessment for Nursing Facility Beds

For the purpose of this plan, the time frame for assessing need is from the baseline year of 2002 (which represents the most recent long-term care data for which reliable U.S. Census population projections are available), to the year 2006.

The need for NF beds in each county of the state shall be calculated as follows:

2007 NF Bed Need = Ó (x) $_{2007}$Bx * $_{A}$Px

where:

$_{2007}$ Bx = resident population totals, by age x, for target and contiguous counties in 2007; x = 0-64; 65-74; 75-84, 85+

$_{A}$Px = Probability that a resident of a given age group will become a patient. This is calculated as:

Number of patients by age group in Target County / $_{2002}$Bx,

where $_{2002}$ Bx = resident population totals, by age x, for target and contiguous counties in 2002; x = 0-64; 65-74; 75-84, 85+

Review Criteria

An application for nursing facility beds shall be consistent with this Plan only if the number of beds being applied for is equal to or less than the net 2007 county NF bed need.

[1] NH beds in Continuing Care Retirement Facilities and Long-Term Care beds in state and federal facilities are not included in any NF bed need calculations under this Plan.

Personal Care Beds

Review Criteria

An application for a certificate of need for additional personal care beds in a county shall be consistent with this plan provided that the applicant can demonstrate that the number of already existing certificate of need approved or licensed personal care beds in the county is insufficient to provide placement for those persons seeking personal care placement in the applicant's county of location.

Intermediate Care Facilities for the Mentally Retarded and Developmentally Disabled

Definition

Intermediate care facilities for mentally retarded and developmentally disabled persons (ICF-MR/DD) provide services for all age groups on a 24 hour basis, seven days a week, in an establishment with permanent facilities including resident beds for persons whose mental or physical condition requires developmental nursing services along with a planned program of active treatment. The facility provides special programs as indicated by individual care plans to maximize the resident's mental, physical, and social development in accordance with the normalization principle.

Review Criteria

No ICF-MR/DD beds to serve persons with mental retardation who need that level of care shall be approved under this plan.

NEW TECHNOLOGY

Definition

New technology includes new technological equipment or services not previously provided in the state and not otherwise covered in the State Health Plan that involve a capital expenditure that exceeds the capital expenditure minimum or equipment that exceeds major medical equipment minimum, and has an annual operating cost greater than $500,000, or new technology where the medical literature indicates that certain utilization levels or procedural volumes are necessary to achieve desirable patient outcomes.

Review Criteria

An application for a CON for new technology shall be consistent with the State Health Plan if the following criteria are met:

1. The applicant shall document that, based on the medical literature, the proposed new technology is efficacious.

2. The applicant shall document that the equipment is certified for its proposed use by the United States Food and Drug Administration (FDA).

3. Preference shall be given to proposals that involve multi-institutional arrangements by contract, agreement, ownership, or other means between two or more agencies to coordinate services, share support services, or provide services on a geographically integrated basis. A party to a multi-institutional arrangement shall not establish its own service or participate in another arrangement for the service until the original service is operating at sufficient capacity for adequate efficiency and quality of care. If the projected use of the new service includes expected referrals from others, the referring parties should be included in the multi-institutional arrangement, if possible.

4. Preference shall be given to proposals that place the new technology in a medical school or other teaching or research facility. New technology designed for pediatric use or proposed for use by pediatric patients shall be approved only in pediatric teaching facilities which have the availability of physician specialty support and specialized ancillary support services.

5. Before acquiring new technological equipment, applicants shall have complementary diagnostic and treatment services available to support the new program.

6. In cases where specific professional standards have not yet been formulated, applicants shall demonstrate that personnel who will staff the new technology are qualified and adequately trained. The applicant shall specify how personnel will be trained in the use of the specific equipment and safety procedures to follow in the event of an emergency. The institution providing the new services shall document its plan for providing

continuing education for referring physicians and institutions in the use of the new technology.

7. Applicants acquiring new technological equipment shall report utilization and demographic data necessary to evaluate the technology and to facilitate state planning.

Private Duty Nursing

Definition

A private duty nursing agency is an entity in the business of providing licensed nursing care to patients in his or her home for a continuous block of time, in increments of at least four (4) hours, in which the private duty nursing agency supervises nursing care provided by agency personal.

Review Criteria

An application for a certificate of need to establish a private duty nursing service shall be consistent with this plan, only if the applicant is proposing to establish or expand private duty nursing services in a county that does not have a licensed or certificate of need authorized private duty nursing service provider or a licensed or CON approved home health agency.

Prescribed Pediatric Extended Care

Definition

A Prescribed Pediatric Extended Care Center is a non-residential health care service that provides an important link in the continuum of care for medically or technology dependent children. The Prescribed Pediatric Extended Care Center provides the following triad of necessary services for dependent children and their parents: day health care, development interventions, and parental training.

Review Criteria

No application for a Prescribed Pediatric Extended Care Center shall be approved under this plan.

Positron Emission Tomography (PET)

Definition

The abbreviation PET stands for positron emission tomography. Positrons are positively charged electrons that are produced spontaneously as certain radioactive substances (for example, radioactive glucose) decompose. These radioactive substances, or tracers, are created in special facilities called medical cyclotrons. The type of tracer used for a particular PET scan varies, based on the medical condition for which a patient is being tested. The tracers have a very short half-lives, which means that they decay rapidly into non-radio-active form. Thus, radioactive material is inside the patient for only a very short time, and the total dose of radiation is equal to and sometimes even less than many other kinds of X-ray procedures. A tomograph is and imaging device, or camera, that obtains sectional views through a patient's body. PET scans combine Nuclear Scanning with chemical analysis to enable physicians to observe how organs work. During a PET scan, a radioactive material is introduced into the patient's body (usually by injection), and is detected by a sophisticated camera.

Review Criteria

No application for Positron Emission Tomography services shall be approved under this Plan.

This criteria shall not apply to any health facility that, on or prior to the effective date of this Plan, has established PET services through a fixed or mobile unit or has entered into a binding agreement pursuant to which the health facility will commence offering PET services through a fixed or mobile unit.

Primary Care Centers with Out-Patient Diagnostic & Surgical Services

Definition

A "Primary Care Center with Out-Patient Diagnostic & Surgical Services" is a public or private provider-based institution with permanent facilities on a single campus, that is under the supervision of an organized medical staff and that is comprised of components for the provision of primary care, ambulatory surgery, twenty-four hour emergency care, and radiologic and magnetic resonance imaging.

Review Criteria

An application for a certificate of need to establish a Primary Care Center with Out-Patient Diagnostic and Surgery Services shall be consistent with this Plan if the health facility:

1. Shall provide primary care services, twenty-four (24) hour emergency services, diagnostic imaging including magnetic resonance imaging services, ambulatory surgical services, and such other outpatient services as necessary to serve the needs of the residents of a county if there are no review criteria for those other outpatient services in the state health plan; and

2. Shall be located in a county that has no hospital, that has a population of sixty thousand (60,000) or more persons, and that also is a medically underserved area as determined by the Secretary of the Federal Department for Health and Human Services.

Only one Primary Care Center that meets the criteria in Paragraphs 1 and 2 above shall be established in each county.

Pilot Project for Primary Angioplasty in Hospitals Without On-Site Open Heart Surgery

Purpose

A three (3) year pilot project on the performance of primary angioplasty is hereby established for purposes of assessing the safety, efficacy, and cost effectiveness of the performance of primary angioplasty in hospitals without on-site open heart surgery, and for purposes of determining if the requirement for on-site open heart surgery should be removed from the State Health Plan criteria for approval of applications seeking to establish or expand therapeutic cardiac catheterization services.

Participation

Participation in the pilot project shall be limited to two (2) hospitals: one (1) from western Kentucky and one (1) from eastern Kentucky. For purposes of this pilot project all hospitals located in Area Development Districts 1 – 6 shall be considered to be in western Kentucky and all hospitals in Area Development Districts 7 – 15 shall be considered to be in eastern Kentucky.

Letters of Intent, Applications, and Filing Fees

1. Letters of intent shall be filed with the Certificate of Need Office on or before May 31, 2004.

2. Applications shall be filed with the Certificate of Need Office, accompanied by a filing fee of two thousand five hundred dollars ($2,500.00), on or before June 30, 2004.

Review Criteria

In order to be consistent with this Plan, an applicant for a certificate of need to establish a pilot project for primary angioplasty in a hospital without an on-site open heart surgery program shall:

1. Be a licensed acute care hospital,

2. Be located further than 30 vehicular highway/road minutes from a hospital with an on-site open-heart surgery program,

3. Have operated a fixed site cardiac catheterization service, a minimum of 5 days/week, 8 hours/day for a period of not less than 3 years,

4. Document that based on the health status of the population served by the hospital, the hospital will perform a minimum of thirty-six (36) primary percutaneous coronary

intervention (PCI) procedures per year. Such documentation shall include, but need not be limited to:

a. the number of patients/year with a diagnosis of ST-segment elevation AMI (including new or suspected new LBBB, thrombolytic eligible and ineligible) that presented at the hospital in calendar years 2002 and 2003,

b. the number of patients that presented at the emergency room with a diagnosis of AMI for the months April and May of 2004,

c. the number of doses of thrombolytic medication, issued through its pharmacy, to patients with a diagnosis of AMI in calendar years 2002 and 2003.

5. Document:

a. that the program will be established and will operate in compliance with the American College of Cardiology/American Heart Association Guidelines for Primary Percutaneous Coronary Intervention Without On-Site Cardiac Surgery; and

b. that primary angioplasty services will be available 24 hours per day, 7 days per week, 52 weeks per year.

6. Document that an agreement has been reached with an ACLS-capable ambulance service which requires the ambulance service to respond to a call from the participating hospital in less than 30 minutes.

7. Document that a statement of informed consent for the performance of a cardiac catheterization procedure and possible angioplasty shall be obtained from each patient consistent with the policies and procedures of the hospital. The informed consent shall disclose to the patient that the hospital is participating in a pilot project, the risks associated with performing primary PCI without open-heart backup, and the alternatives available. The signed "informed consent" form is to be archived in the patient's hospital chart.

8. Document compliance with the staff requirements set out at Appendix A of this Plan.

9. Document compliance with the training requirements set out at Appendix B of this Plan.

10. Document that a written collaborative agreement with an in-state tertiary hospital which meets the requirements of Appendix C of this Plan has been entered into.

11. Agree in writing to comply with the data reporting requirements set out at Appendix D of this Plan.

Appendix A

Staffing Requirements for Primary Angioplasty Programs in Hospitals Without On-Site Open Heart Surgery

Hospitals participating in the pilot project for primary angioplasty in hospitals without on-site open heart surgery shall have at least two Board certified or Board eligible interventional cardiologists on the staff who meet the Proficiency in Coronary Interventions standards of the American College of Cardiology (ACC) and who will participate in the performance of primary angioplasty procedures at the pilot project hospital. In each of the previous 2 years each of these physicians shall have performed no fewer than 100 cardiac catheterization procedures (total diagnostic and therapeutic). At least 75 of the 100 required procedures must have been angioplasty procedures unless these procedures were being performed at a facility with a volume of greater than 400 angioplasty procedures per year. Each of the physicians participating in the pilot project will maintain credentials at a hospital at which that operator performs elective angioplasty procedures.

All physicians performing PCI at a pilot project hospital shall:

1. Continue to perform no fewer than 100 cardiac catheterization procedures/year (total diagnostic and therapeutic). At least 75 must be angioplasty procedures, unless the procedures are being performed at a facility where more than 400 angioplasty procedures are performed per year.

2. Maintain credentials at a hospital at which that operator performs elective angioplasty procedures.

All staff involved in providing PCI, including the interventional cardiologists, nurses and technicians must have a current ACLS certification.

Each participating hospital shall have staff and services consistent with the Clinical Practice Guideline Number 10 "Unstable Angina: Diagnosis and Management" published by the Agency for Health Care Policy and Research, to include:

1. Continuous staffing of the emergency department by personnel competent in performing an ECG, initial evaluation and treatment of patients with acute ischemic syndromes including myocardial infarction and unstable angina. Appropriate monitoring equipment will be available, staff will be trained in cardiac monitoring and ACLS, and staff will maintain current ACLS certification.

2. The ability to provide routine lab testing and radiographic studies.

3. Maintaining an intensive care unit nurse to patient staffing ratio of 1:1 or 1:2, cardiac monitoring, immediate access to persons trained in ACLS; and capabilities for arterial line and pulmonary artery catheter placement, temporary pacemaker placement and mechanical ventilation. ICU staff are competent in the administration

of all forms of vasoactive continuous IV infusions. Nursing staff are competent in the recognition and treatment of arrhythmias and evaluation of ischemic symptoms.

4. Having intra-aortic balloon equipment and staff trained in the use of this equipment immediately available.

5. Having an intermediate care unit:

   a. with a nurse to patient ratio of 1:3 to 1:5;

   b. which provides continuous ECG monitoring and prompt access to personnel trained in ACLS, with current ACLS certification.

   c. with personnel who are competent in recognition of arrhythmias and evaluation of ischemic symptoms; in the administration of some forms of vasoactive drips [e.g., low-dose dopamine, dobutamine, or nitroglycerine (NTG) infusion; and in the care of patients with a temporary pacemaker already in place.

Appendix B

Training Requirements

Written policies and procedures regarding establishing, maintaining and monitoring proficiency standards for all of the interventional cardiologists members of the team performing primary angioplasty at the pilot project hospital shall be submitted as an attachment to the application for participation in the pilot project .

Written assurance that all staff that are hired after the completion of the initial training at the pilot project hospital will complete a training program that mirrors the initial training program shall be submitted as an attachment to the application for participation in the pilot project. The relevant collaborating tertiary and pilot project hospitals will develop this training program.

Training of all staff (including, at a minimum, all interventional cardiologists, nurses and technicians) shall be performed on the intra-aortic balloon pump annually.

Appendix C

Data Collection

Pilot project hospitals must participate in the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) quality measurement program and shall report outcome results to the Cabinet quarterly. Such reports shall be due on March 31, June 30, September 30 and December 31 of each year.

All hospitals participating in the pilot project shall:

1. Maintain a log of all patients that present with a diagnosis of AMI or R/O AMI to the emergency department of the hospital and the treatment administered.

2. Collect and archive all pertinent data on site in an easily retrievable manner. These forms will not be collected by the cabinet but may be subject to audit.

3. Follow-up on all patients entered into the pilot project at 1 month, 6 months and one year after the initial hospitalization.

4. Data collection, required by the cabinet, will be complete and archived at the pilot project hospital. The data will be maintained in an easily retrievable manner to be retrieved when requested by the department or any designated agent of the department. Patients records shall be maintained according to 902 KAR 20:016 3(11)a.

The cabinet may, from time to time, require review of a sample of patients cared for under the provisions of the pilot project.

Appendix D

Collaborative association with tertiary hospital.

All hospitals participating in the pilot project shall:

1. establish a collaborative association with an in-state tertiary hospital to specifically meet the requirements of the pilot project,

2. document that current collaboration agreement has been signed with a tertiary hospital, and

3. include the collaborating tertiary hospital as one of its referring facilities.

The purpose of this association is to provide the pilot project hospital's staff ongoing support and expertise in the care of patients undergoing a primary angioplasty procedure.

The tertiary hospital must be either a university hospital or a hospital performing a minimum of 300 cardiac surgeries per year.

Responsibilities of the tertiary hospital shall, at a minimum, include:

1. Provision of ongoing, 24 hour availability of consultation to the physician and nursing staff in the care of patients that are candidates for and/or have primary angioplasty.

2. Development with and participation in a joint performance improvement program, with the participant hospital, which includes all disciplines providing patient care (i.e., physicians, nurses, technicians, and administrators from the staffs of both the participating pilot project hospital and the collaborating tertiary hospital) and focuses on patient outcomes.

3. Provision for occasions of clinical training, at the tertiary hospital, of the staff of the pilot project hospital in preparation for performing primary angioplasty at the pilot project hospital.

4. Development with the participant hospital of a training program for all staff (including, at a minimum, all interventional cardiologists, nurses and technicians) that are hired after the completion of training at the pilot project hospital. The training program will mirror the initial training program.

5. Development with and participation in joint in-service education programs for all disciplines providing patient care (including physicians, nurses and technicians) at the pilot project hospital. The in-service education programs will be based upon needs identified in the processes of staff evaluation and the performance improvement program.

The collaboration agreement shall:

1. Be specific to the requirements of the pilot project and be developed through the participation of all appropriate disciplines. At a minimum, this includes physicians, nurses and hospital administrators from the staffs of both the participating pilot project hospital and the collaborating tertiary hospital.

2. Delineate the development of a joint performance improvement review program which includes physicians, nurses and administrators from the staffs of both the participating pilot project hospital and the collaborating tertiary hospital and focuses on patient outcomes.

3. Delineate the development of joint educational programs to include all groups of staff (physicians, nurses and technicians) at the pilot project hospital.

4. Include specific provisions for the emergency and routine transfer of patients.